



Office of Management and Systems

Annual Performance Report

Fiscal Year
2000



December 29, 2000

Dear Colleague:

I am pleased to share with you the Food and Drug Administration (FDA), Office of Management and Systems' (OMS') fifth annual performance report. This report highlights OMS/Agency accomplishments during fiscal year 2000 and is intended to let our customers and partners know what we have done and are doing to help support the Agency's public health mission.

Fiscal year 2000 was very productive for the OMS team. Contract negotiations with NTEU, which began in fiscal year 1999, ended in the beginning of fiscal year 2000 with a contract signing ceremony with the Deputy Secretary of HHS, Kevin Thurm; the Commissioner of FDA, Jane E. Henney, M.D.; and the President of NTEU, Colleen Kelley. NTEU and FDA worked just as productively toward establishing the FDA/NTEU Partnership Council, which ended FY 2000 with a signing ceremony with the President of NTEU and myself.

FY 2000 also marked the beginning of the Agency-wide strategic workforce planning initiative aimed at providing a strategic focus on the Agency's workforce requirements and initiating recruitment, retention and workforce development strategies needed to remain competitive. Maintaining a competitive, science-based workforce is one of the Agency's top priorities.

The Agency's financial statements, for the second year in a row, received an unqualified or "clean" opinion from independent auditors. The clean opinion helped assure the public that the Agency is meeting the growing demands of its public health mission in a business like manner. The auditors' opinion and the business like manner in which the Agency operates helped pave the way for the Department and OMB to approve an additional \$29 million to help make Y2K compliance the success that it was for FDA. Strong leadership and great teamwork throughout the Agency earned us high marks for Y2K compliance.

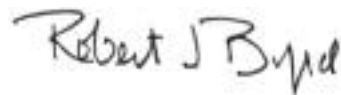
In addition, OMS realized approximately \$14 million in cost savings/avoidance through innovative procurement methods and, where possible, re-negotiating contracts for more favorable terms. Through good contract negotiations, and working closely with our Center

Directors and Executive Officers, we were also able to meet our shifting space needs and the challenges of meeting our headquarters' space requirements in 40 buildings we occupy throughout the greater Washington, D.C. area. We accomplished this successfully while still focusing on the long range consolidation of FDA headquarters at College Park and White Oak, and the consolidation of FDA field locations throughout the nation.

The accomplishments of the OMS team are reflective of the cooperation and commitment of senior management and the collective efforts of the entire FDA workforce. I would like to thank my colleagues within OMS, the Agency, and the Department for their assistance. I especially thank the Agency's Executive Officers and their staffs for their essential contribution to the Agency's corporate success.

It has been a privilege to have worked with the many talented and dedicated individuals who have contributed to FDA's accomplishments. The OMS Team looks forward to the year ahead and in continuing to play a vital role in supporting the Agency's public health mission. During the Presidential transition and into a new Administration, we will meet the challenges which lie ahead. If you have any questions or comments about this report, you can reach me on (301) 827-3443 or at my e-mail address: rbyrd@oc.fda.gov.

Sincerely,

A handwritten signature in dark ink, reading "Robert J Byrd". The signature is written in a cursive, slightly stylized font.

Robert J. Byrd
Deputy Commissioner for
Management and Systems
Chief Financial Officer

Table of Contents

EXECUTIVE SUMMARY	i
PROGRAM SUMMARY	1
MAJOR ACCOMPLISHMENTS IN FY 2000	4
People	4
• Strategic Workforce Planning Initiative	
• Quality of Work Life Initiatives	
• Partnering with NTEU	
• Recruitment & Staffing/Automation	
• Diversity Outreach	
• CVM "Master Reviewer" Peer Review Plan	
• Electronic Dockets	
• Partnership for Administrative Quality (PAQ)	
• PDUFA Leadership and Management	
• Federal Managers' Financial Integrity Act (FMFIA)	
Money	8
• Financial Statements	
• Payroll and Budget Management	
• Budget Formulation	
• New Accounting System	
• Travel Manager	
• Central Account	
Things	11
• Agencywide Operation Cost Savings	
• Acquisition Outreach Activities	
• Acquisition Streamlining Initiatives	
• Space Management Reengineering	

- Streamlining Through Automation
- HQ Space Acquisition, Lease Renewals, and Extensions
- ORA Space Acquisition, Lease Renewals, and Extensions
- Headquarters Consolidation
- Arkansas Regional Laboratory
- New York (Jamaica, Queens) Laboratory
- Los Angeles (Irvine) Laboratory
- Decommissioning of FDA Laboratory Facilities
- Environmental, Health, and Safety Program
- Technology Transfer/Leveraging
- CFO Audit of the Property Management Program
- Management of Physical Security

Systems 20

- Agency Information Management System (AIMS)
- Telecommunications
- Information Technology Security
- Year 2000 Compliance
- Enterprise Administrative Support Environment (EASE)
- IT Investment Management
- Internet/Intranet Services and Support
- Information Technology Investment Management

MAJOR CHALLENGES FOR THE FUTURE 25

FOR MORE INFORMATION 34

Executive Summary

Last year, OMS identified several priority initiatives for FY 2000 and beyond, including:

- *Upgrading or replacing the Core Accounting System, which supports all of FDA's financial activities*
- *Developing more sophisticated payroll projection models*
- *Completing the fiscal restructuring of the Office of the Commissioner*
- *Reducing by 5 percent, or \$2.8 million, the FDA Central Account*
- *Continuing to work with GSA to accomplish the Headquarters consolidation project at White Oak*
- *Implementing suggestions and recommendations resulting from the Division of Real Property Management re-engineering efforts*
- *Establishing a facilities help desk*
- *Assessing the risk of systemic and planned attacks from the Internet*
- *Responding to the challenging and expanding requirements to receive and transmit applications and related data electronically*
- *Beginning to transition long distance voice services, wide area network, "800" services, and credit card services to the new long distance contract*
- *Continuing a cooperative relationship with NTEU to provide successful partnering and pre-decisional interaction with the Union*
- *Continuing efforts to improve the Quality of Work Life for FDA employees*
- *Institutionalizing the Strategic Workforce Planning Initiative*

As a result of Agencywide cooperation and the efforts of the entire FDA management team, we were able to achieve most of our FY 2000 goals in these areas, and we are

pleased to share these and other major accomplishments with you in this report.

In FY 2001 and beyond, OMS must address additional challenges, particularly in financial and resource management, to ensure that we continue to provide high quality services in a time of tight fiscal constraints. To that end, OMS will continue the cost-saving and cost-avoidance initiatives currently underway, and will initiate further improvements including:

- *strengthening relationships with Appropriations Committee Staff and others*
- *providing Center managers with the tools to efficiently manage payroll resources through web-based technology*
- *leveraging a Department-wide financial systems workgroup effort to review financial system models for FDA and other OPDIVS who are replacing their core accounting systems*
- *continuing support for facilities improvement efforts including Los Angeles Laboratory construction, White Oak project planning, MOD I and Beltsville Research Facility renovations, and the College Park move*
- *expanding the existing automated facilities management system to an Agencywide system through the web capabilities of new enhanced software*
- *strengthening defenses from cyber terrorism, including the development of an Agency Critical Infrastructure Protection Plan*
- *developing and implementing a comprehensive secure remote access system for the Agency*
- *promoting the complete implementation of Information Systems Architecture components by the entire Agency*
- *rolling-out the Strategic Workforce Planning initiative*
- *continuing efforts to successfully partner with the National Treasury Employees Union*
- *enhancing retention of drug reviewers and other key members of our technical and science-based workforce by implementing ideas that come from a series of focus group meetings*

Program Summary

•• Who We Are ••

The Office of Management and Systems is the business arm of the Food and Drug Administration. OMS consists of four major components concentrating on the effective and efficient management of "people, money, things, and systems." We are an organization of more than 400 employees, including professional staff of accountants, engineers, architects, administrators, and computer scientists who serve the Agency's approximately 9,000 employees nationwide. The OMS team, as we are referred to, includes the Office of the Deputy Commissioner for Management and Systems; the Office of Human Resources and Management Services; the Office of Financial Management; the Office of Facilities, Acquisitions, and Central Services; and the Office of Information Resources Management. We are an integral part of the top FDA management team and provide leadership, guidance, and solutions to a wide and varied number of management and resource issues facing the FDA. Above all, we are a customer-focused organization, supporting the management of the Agency's resources in a collaborative, coordinated, and cost effective fashion.

•• What We Do ••

PEOPLE: We provide a wide range of human resource and management services to FDA employees. Most employees work in the greater Washington, D.C. area, but almost 3,000 scientists, technicians, and staff are located in field offices from Maine to Hawaii and Puerto Rico to Alaska. Our quality personnel services include staffing the Office of the Commissioner, and Agencywide programs for recruitment and retention, position classification policy, compensation, training, awards, performance management, employee relations, labor relations, and ethics. We also administer FDA's Delegations of Authority and Organizational Policy programs, oversee FDA's Internal Controls programs, and provide public access to FDA's regulatory dockets.

MONEY: We provide resource management leadership and a full range of professional financial services throughout FDA. OMS serves as the focal point for Agencywide financial management including budget planning, preparation, formulation, presentation, execu-

tion and control; accounting, payment processing, financial reporting, foreign and domestic travel management, employee relocation, and payroll liaison; and financial systems development, maintenance, coordination, and integration. We develop, present, monitor and track an annual total budget of \$1.3 billion, which includes two direct appropriations and four separate and unique user fee activities. We pay more than 130,000 invoices per year, and process vendor payments of more than \$280 million, with more than \$230 million made via wire transfer. We develop, operate, maintain, and continuously update FDA's central financial systems. We manage FDA's annual budget hearings with DHHS, OMB, and the House and Senate Appropriations Subcommittees.

THINGS: We provide an efficient and effective program of nationwide logistical support for FDA in the areas of real and personal property, purchasing, grants, physical security, engineering services, environmental, safety, health, and long range planning for the Agency's future facilities. This involves significant resources including annual lease costs of \$ 106.6 million, and owned facilities valued at \$ 132.7 million. We manage 343 government owned or leased buildings and facilities nationwide, totaling 4.2 million square feet (LEASED ONLY). In addition, we manage 49,000+ line items of personal property with an acquisition cost of \$ 237.3 million. In FY 2000, the contracting program totaled \$ 159.7 million in contracts, \$ 102.8 million in simplified acquisitions, \$ 24.1 million in International Merchant Purchase Authorization Card (IMPAC) transactions, and \$ 25.3 million in grants.

SYSTEMS: We are responsible for building and maintaining an information technology (IT) infrastructure and ensuring interoperability of FDA systems and support of a wide-area network that includes 133 routers. We develop systems that account for approximately 40% (\$57 million) of the FDA's \$147 million total IT budget. Approximately 20% (\$11 million) of the development project investments are facilitated through the Agency's Information Technology Investment Review Board process. We coordinate Agencywide IT and business life-cycle management activities such as strategic business planning. We support management of the Agency's Internet and Intranet sites, which includes the management of 30 million hits to the Internet site each month, 40 web-enabled databases, and 300,000 posted documents. In addition, we provide IT services to support programmatic and administrative operations. These services include telecommunications support, information collection, information dissemination, records and forms management, IT policy development, and information technology security.

• • Why We Do It • •

By providing cost-effective oversight and support services either centrally or distributed, OMS helps all FDA components save money and staff. Because of the tight fiscal constraints under which the Agency operates, we continue to encourage or direct the investment of Agency resources in areas that will return the greatest benefit in supporting the Agency's public health mission. Our goal for the next three years ending FY 2003, during which the Agency is expected to be impacted by the balanced budget agreement, is to provide strategic guidance on how FDA can best defend and support its budget requests; to oversee the strategic management of Agency resources and business practices; and to continue to reduce the cost of Agency support services. OMS is evolving from a support and customer service role to that of business and strategic partner. We strive to provide cost-effective oversight, and to promote efficient, consistent, customer focused support services, that utilize best management practices from a corporate perspective to help the Agency accomplish its mission.

Major Accomplishments in FY 2000

•• People ••

STRATEGIC WORKFORCE PLANNING INITIATIVE. Coordinated the first Agencywide workforce planning initiative designed to engage FDA leadership in a systematic process for anticipating future workforce requirements and planning ways to fill the gaps between existing resources and future requirements. FY 2000 accomplishments include:

- Established a Working Advisory Group with representatives from each Center/ORA and OC and NTEU.
- Conducted interviews with top Agency officials and external customers, and held focus groups at HQ and in the Field to gain insight into the workforce competencies that will be needed in the future, how we can grow and acquire our future workforce, and what we need to do today to prepare.
- Developed a Strategic Workforce Planning Guide that provides recommendations and action items related to the key areas of: Leadership Development; Workforce Development; Recruitment and Retention Strategies; Science Workforce Development; Workforce Skills; and Workforce Leveraging.
- Participated as strategic partners in the budget planning process to ensure that workforce planning strategies were considered.

QUALITY OF WORK LIFE INITIATIVES. Worked to institutionalize the concept of strengthening the quality of employee work life. FY 2000 accomplishments include:

- Convened focus groups to identify quality of work life issues that impact on Agency scientists. The recommendations from these focus groups were consolidated with the information gathered from the focus group with the Committee for the Advancement of FDA Science (CAFDAS) conducted under the Strategic Workforce Planning initiative. They provide the basis for action items under the key areas of Scientific Workforce Development in the Strategic Workforce Planning Guide.
- Coordinated the design, development and implementation of an Agencywide Administrative Management Development Program to enhance administrative management skills through a sequence of training and other developmental activities.

- Collaborated with the Office of Regulatory Affairs (ORA) in addressing the developmental needs of ORA supervisors. Supervisors from across the Central Region participated in an assessment of the supervisor's "current state" and the desired "future state," and recommendations were made to enhance the quality of work life for first-line supervisors as well.
- Assisted in the design and successful implementation of the HHS sponsored Diversity Conference. Representatives from FDA included bargaining unit and non-bargaining unit employees.
- Established an Agencywide team in April 2000 to explore new ways to enhance communications throughout FDA. The team was comprised of 50 geographically dispersed members, and worked in full partnership with the National Treasury Employees Union. The team developed more than 30 recommendations for enhancing FDA communications and identified 17 as priorities to be implemented in FY 2001.

PARTNERING WITH THE NATIONAL TREASURY EMPLOYEES UNION (NTEU).

Continued successful implementation of the Collective Bargaining Agreement (CBA). The principles of interest-based problem solving and partnership enabled the cooperative working relationship between FDA and NTEU in FY 2000. Accomplishments include:

- Developed and implemented the FDA Transit Subsidy Program. Currently, 975 FDA employees participate in the program.
- Established joint FDA/NTEU committees to develop the FDA Gain Sharing Program and redesigned the FDA Suggestion Program.
- Established joint FDA/NTEU National Health and Safety Committee and National Divestiture Committee.
- Established the FDA Partnership Office. A management representative and an employee representative staff this office on a full-time basis. They successfully mediated/decided disputes regarding Alternative Work Schedules and Flexible Work Place Arrangements per the CBA. They also resolved several unfair labor practice complaints and other problems between management and the union prior to escalation into official grievances.
- Established the FDA/NTEU Agency Partnership Council and developed a Partnership Strategic Plan outlining goals and objectives.

RECRUITMENT & STAFFING AUTOMATION. Initiated an evaluation of the current automated system commonly known as Direct Hire and Merit Promotion, which facilitates the tracking and handling of employment applications. The current system is no longer supported by Oracle and will face technical support problems and increased maintenance costs issues in the coming years. Based on this information, initiated an evaluation of Commercial-Off-The-Shelf systems that offer greater functionality than the Direct Hire and Merit Promotion system. These systems are capable of automating the entire staffing process, resulting in an easier process for applicants to apply for jobs, more timely job offers, and reduced costs.

DIVERSITY OUTREACH. Increased the number of Hispanic Association of Colleges and Universities (HACU) student interns on board for the summer of 2000 eight-fold, from 2 in FY 99 to 16 in FY 00. Facilitated the hiring of five disabled college students for the summer under the Work Recruitment Program, compared to one in FY 99. Hired thirteen Historically Black Colleges and Universities (HBCU) student interns as well.

Facilitated the Hispanic Recruitment, Retention and Advancement (HRRA) Work Group which included the production of an action plan and report for the Commissioner. As a result, the Commissioner established a Senior Advisory Board on Hispanic Initiatives charged with making decisions on the implementation of action plan recommendations

CVM "MASTER REVIEWER" PEER REVIEW PLAN. Established a master reviewer peer review plan, in conjunction with Center management, for reclassification of some CVM regulatory review scientists to grades GS-14 and 15. This plan, which is similar to the CDER master reviewer plan, has been completed and will be operational this Fall following training for all covered employees and peer review committee members.

ELECTRONIC DOCKETS. Initiated new Internet processes of accepting comments electronically and allowing the public to electronically register for public meetings. This effort saved the American public both time and effort in keeping up with and responding to FDA's regulatory programs. Many enhancements to FDA's Dockets Website improved access to FDA data and expanded the amount of material available on the Internet. Starting in January 2000, we began posting Advisory Committee Briefing packages on the Web, as required by a stipulation in a court case. The number of pages viewed on the Dockets Website jumped from approximately 500 million in FY 1999 to 3.6 billion in FY 2000. Agency components benefit from the electronic documents by receiving critical rule-making documents via e-mail in a timely manner.

PARTNERSHIP FOR ADMINISTRATIVE QUALITY (PAQ). Implemented a new process in FDA for providing systematic oversight of FDA's internal control of administrative

programs. Working in full partnership, OMS and the Centers designed and implemented this PAQ program which was kicked off at the Management Operations Meeting on October 14, 1999. Each Center is working within the same guidelines to conduct a customized review of administrative programs within its organization. Areas covered under the PAQ program include: personnel, physical security, financial management, property management, procurement, and information technology security.

PDUFA LEADERSHIP AND MANAGEMENT. The Deputy Commissioner for Management and Systems initiated and regularly convenes periodic meetings to develop, analyze and implement innovative ways to improve management and enhance performance under PDUFA. These meetings include the Executive Officers of CDER, CBER, and ORA as well as OMS senior staff. A number of innovative proposals to enhance recruitment, retention, and information technology supporting drug application review have come out of these meetings. One outcome is a series of focus groups with drug application reviewers and managers scheduled early in FY 2001. These focus groups will elicit their views on critical factors impacting on reviewer quality of work life, and on reviewer decisions to remain at FDA or to accept offers elsewhere.

OMS also led a cooperative effort with CDER, CBER, ORA, and other OMS components in updating the PDUFA II Five-Year Plan in FY 2000. The FY 2000 updating of the plan allows 227 more staff-years to be expended by the final year of the plan, taking advantage of revenues carried over from previous periods and other savings. This assures CDER, CBER and ORA the staffing and resources necessary to meet the PDUFA II goals, which become substantially more difficult during the final two fiscal years, 2001 and 2002. Finally, OMS played a major role in preparing materials and analyses used in the public meeting on PDUFA that the agency conducted on September 15, 2000.

FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT (FMFIA). Re-engineered the FMFIA annual reporting process to relieve administrative burdens on both the Centers and Offices for the FY 2000 report and subsequent years. This concise format should substantially improve the quality of the information and reduce the size, compared to previous reports, by focusing on specific identification of the management control activities; control mechanisms; intended effects; final results; and corrective actions as applicable. The re-engineered process, designed for electronic submission, will facilitate both the components' report preparation, the Agency review and follow-up processes, and final preparation of the annual submission to the Department. Utilization of the PAQ process, along with other existing activities as sources of information to assess management controls, is encouraged to enhance the new FMFIA process.

•• Money ••

FINANCIAL STATEMENTS. Received an “unqualified opinion” from independent auditors on the FDA FY 1999 financial statements under the Chief Financial Officers (CFO) Act; received, for the second year in a row, the Department’s CFO Award in recognition of the audit results.

Realigned staff resources to ensure FDA will meet the requirements of the FY 2000 audit by establishing a branch dedicated to the CFO Audit requirements. This reorganization more closely aligns accounting and financial system development resources.

Revised accounting procedures so that accounting records are updated nightly, rather than three times a week, to allow for more timely access to financial information and reduced risk of errors or omissions.

PAYROLL AND BUDGET MANAGEMENT. Completed Spiderman Hyperion rollout of the FTE and Payroll applications to all Centers and most Offices in February 2000. This completed the rollout of the Hyperion software capability to all components for various budget applications, and also provided on-line access to a variety of payroll information applications. Components can utilize the applications to improve the Agency’s overall management of its payroll resources.

Developed Hyperion reports to analyze payroll data at various organizational levels. This allows Centers and Offices to allocate payroll budgets to any level of the organization that they choose, and perform independent analysis of payroll for their Centers at those levels.

Recommended Business Objects (BOs) software as a platform for additional enhancements. This software will enable Agency components to create custom reports based on their organization and management needs. Received funding for the project in March and began work on developing the many reports. (All of the Oracle Web reports, i.e., Overtime, Cash Award, Detail, have been converted to BOs.) Business Objects has been implemented in all the Centers (completed August 2000). The Business Objects included additional reports for the Centers to access as well as some improvements such as easy download capability into Excel. Business Objects is also the software tool being used in the EASE Reporting Analysis (RAM) module. The choice of Business Objects for payroll reporting leverages the EASE/RAM investment in Business Objects in terms of software licenses and user training by virtue of the common users.

Completed follow-up actions to finalize the FY 1999 reorganization of the Office of the Commissioner. OFM provided training and technical support to OC offices to assist them in establishing improved financial control systems for the newly established offices, including payroll management improvements.

BUDGET FORMULATION. Continued to build on the significant increases FDA received in FY 2000 appropriations process through the coordination, development and facilitation of the justification and presentation of the FY 2001 requested increases of \$176 million to Congress. FDA's budget is more complex with the recent addition of multiple cross-program initiatives such as Food Safety, Bioterrorism, and new user fees; which were added to the historical core programmatic public health issues such as Science, Premarket and Postmarket Review and Outreach.

Intensified Congressional outreach to ensure a better understanding of FDA, its mission and its budgetary and programmatic needs. Continued this effort at the forefront of a coordinated Policy, Legislative and budgetary strategy. FDA's Director, Office of Financial Management, the Agency Budget Officer, along with the Senior Associate Commissioner, Office of Legislation, Policy and Planning conducted courtesy visits with representatives from our House and Senate Appropriations subcommittees; provided briefings on the highlights of the FY 2001 budget request to House and Senate subcommittee staff; accompanied the Commissioner on visits with Members of the Appropriations Subcommittees; and maintained contact with House and Senate subcommittee majority and minority staff principals to ensure their understanding of FDA programs and funding needs. In addition, continuously provided an increasing volume of relevant FDA information (detailed statistical data displays, talk and issue papers, press releases, regulations, explanations of program, etc.) to interested Members and staffers. As a result of these efforts, FDA received enhancements in FY 2001 in excess of \$100 million.

Continued to actively develop the working relationship between FDA budget staff, Departmental budget staff, and Office of Management and Budget (OMB) examiners to blend the three organizations into a cohesive team proactively achieving the best for FDA's future funding requirements for the increasingly complex public health initiatives. Progress to date includes briefings, meetings, and tours of all program areas and many field activities for both Departmental and OMB staffers including a visit to the N.Y. District import operations and laboratory.

Coordinated development of several reprogrammings during the year, including a redistribution of PDUFA resources, reallocation of available tobacco resources after the Supreme Court decision, and end-of-year spending decisions which resulted in additional funds to meet the Commissioner's priorities.

Contributed to and participated in Inter- and Intra- Department work groups to support various Presidential and Secretarial initiative; such as, Food Safety, Bioterrorism, Seafood and the Clinical Laboratory Improvements Act (CLIA).

NEW ACCOUNTING SYSTEM. Developed a draft white paper supporting the need for a new accounting system to be implemented over a 3 to 5 year time frame and the

need to upgrade outdated systems that support FDA's financial management. The Accounting System operates on a third generation language, COBOL; the code is more than 30 years old; and expertise is limited to a few individuals with knowledge of COBOL programming. This makes the System difficult to maintain, and limits our ability to make major changes to meet customer needs and to meet new government requirements (measuring costs and performance goals), under the Government Performance and Results Act (GPRA).

Participated in the formulation of a Financial System Workgroup, at the Department level, that conducted an analysis of different financial system modules that are currently in use in other agencies. The efforts of the workgroup will reduce out year costs for the business case development by overseeing the contractor in analyzing the system requirements across the OPDIVS and documenting several viable business solutions.

Developed a project plan, coordinating with OIRM and OFACS on financial systems activities and integration, and a preliminary estimate of out year costs for a new financial management system. The costs and justification information are supporting a request, in the FY 2002 budget process, for funding the new accounting system.

TRAVEL MANAGER. Initiated Phase I of the project using vendor supplied travel software. The project is web based, greatly increasing the chance of successful implementation Agencywide. The goal is an entirely paperless process, with needed receipts and records maintained in the Program Office. Accounting will conduct periodic reviews when the pilot is implemented for the selected offices.

The Office of Information Resources Management ("Systems") has been an active participant in the project and is evaluating the possible integration of Travel Manager with EASE.

CENTRAL ACCOUNT. In an effort to improve customer service and be more communicative with the Centers, provided numerous briefings to the Agency Executive Officers on Central Account costs; i.e., rationale and/or historical context for inclusion in Central and responses to several inquiries for clarification. Coordinated with the Office of Executive Operations on OC costs that should be centralized.

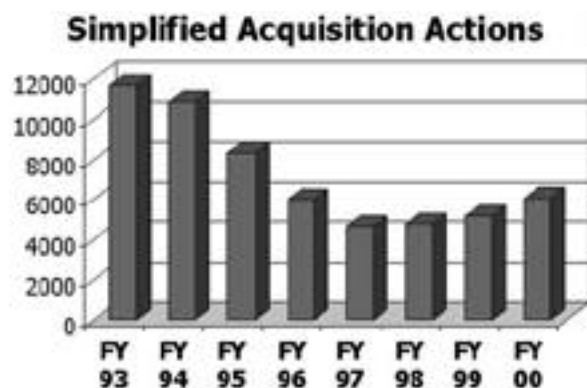
Continued efforts to reduce telecommunications and NIH management fund costs with the goal of reducing central accounts costs as much as possible. Telecommunications costs have decreased in recent years due to the rate of competition in the industry. OFM and OIRM worked together to assure that these savings are captured and could be devoted to other Agency needs. OFM held a series of meetings with NIH staff concerning NIH's new

methods of calculating FDA's contribution to the Management Fund. In particular, FDA has argued that NIH's calculations overstate the costs of supporting FDA's lab space at the NIH campus. FDA has been assured that the calculations will be redone so that FDA's costs will be lower in Fiscal Year 2001.

•• Things ••

AGENCYWIDE OPERATING COST SAVINGS. Realized \$14.1 million in cost savings/avoidance by utilizing innovative financing, contracts, blanket purchase agreements, negotiations and other instruments. These savings resulted from:

<u>Activity</u>	<u>Savings</u>
• Negotiated final overhead rates with a contractor that resulted in a cost saving on five FDA contracts.	\$464,000
• Continued to convert contracts to performance-based work statements.	\$990,507 (est.)
• Streamlined procedures to allow use of the IMPAC Card for renovation with commercial vendors or under existing indefinite quantity contracts at FB-8, MOD I and II and leased facilities metro-wide.	\$99,552 (est.)
• Conducted detailed analyses of GSA's monthly Star rent bills, which revealed several discrepancies. Negotiated with GSA to reduce FDA's rent costs in FY 2000.	\$6.4 million
• Streamlined decommissioning process, reducing time between assessment and remediation by three months, thus decreasing quarterly rent charges.	\$514,316
• Awarded an Agencywide Research Fellowship Program contract. Under the previous method administrative fees totaled as high as 24%. New contract establishes a flat 14.62% administrative fee for the next five years.	\$534,665
• Continued to promote the Bankcard program throughout the agency, utilizing this program as opposed to the small purchase and/or blanket purchase agreement mechanisms to generate savings in administrative costs.	\$5.1 million (est.)



ACQUISITION OUTREACH ACTIVITIES. Continued to promote FDA's Acquisition program to the vendor and peer communities by hosting a Women-Owned and Small Business (WOSB) Seminar and Expo and giving a presentation on best value procurement at a national acquisition conference.

- The WOSB Seminar and Expo was an opportunity for vendors to display materials and discuss their capabilities for future FDA requirements with the objective of increasing opportunities for women-owned small businesses. This outreach accords with an Executive Order and Secretary Shalala's initiative on WOSB.
- Two of our acquisition professionals gave the "best value" presentation at the 2000 Federal Health Care Acquisition Conference in Orlando, Florida in June. The presentation covered processes and specific contracts successfully awarded using best value procedures. FDA continues to be a leader in the use of best value procurement, evaluating tradeoffs between price and quality factors, such as technical ability and past performance. For example, a best value approach was recently used to purchase warehouse and moving services for the D.C. metropolitan area. Although the selected offeror had a higher price than the next ranking competitor, FDA's technical

and past performance evaluation showed that offeror had performed significantly better in the past.

ACQUISITION STREAMLINING INITIATIVES. Included changing the administrative process for state contracts and consolidating the subscription services for FDA headquarters.

- Converted approximately 69 state contracts under \$100,000 to simplified acquisition procedures; invoices and progress reports will now bypass the contracts office and go directly to the finance and program offices. This will reduce staff hours necessary for the administration and close-out process for these actions.
- Awarded a single contract to provide for FDA Libraries Serials (Subscription Services) for CDRH, CFSAN, and FDA Medical Library (CDER). CBER does not have a library, but will order subscriptions under the contract.



SPACE MANAGEMENT REENGINEERING. Developed 31 recommendations through an Agencywide reengineering workgroup. When implemented, substantial time savings will be realized in many of the reengineered processes. For example, each space renovation project is expected to be reduced by two weeks due to the process changes. Also, additional authorities to perform day to day operations were granted to the Centers. The establishment of a facilities help desk that was identified as a challenge for FY 2000 was one of the processes that was included in the reengineering effort. The facilities help desk will be established as part of the implementation of the reengineering recommendations and will be completed during FY 2001.

STREAMLINING THROUGH AUTOMATION. With the replacement of the Property Management Information System (PMIS) and enhancements to the facilities management system, we are providing automated tools that will improve customer service and our processes.

- The implementation of a facilities management system is one of the reengineering team's recommendations. FDA has purchased software to expand the existing facilities management system to an Agencywide system through the web capabilities of the enhanced software version. The new system (Facility Center) will allow OFACS and the Centers to maintain a comprehensive database on all FDA facilities nationwide, to include CAD drawings where available for space planning and design, help desk capabilities, building operations and maintenance information, building leases and pertinent lease information.
- The in-house PMIS has been replaced with PeopleSoft's Asset Manager product. We continue to improve the property process by developing interfaces between the Purchasing System and the Property System; and between the Property System and the General Ledger.

HEADQUARTERS SPACE ACQUISITION, LEASE RENEWALS AND EXTENSIONS.

Acquired 83,100 square feet of space for the Agency.

- CVM - 18,200 square feet in 7519 Standish Place.
- CFSAN - 7,900 square feet in 1110 Vermont Avenue.
- CBER - 6,000 square feet in 11400 Rockville Pike.
- CDRH - 51,000 square feet in 801 Thompson Avenue
- OCI Metro Washington Field Office; Falls Church, VA Resident Post; OCI Washington Resident Office; 1401 Rockville Pike; and 2094 Gaither Road.

ORA SPACE ACQUISITION, LEASE RENEWALS AND EXTENSIONS.

- Leased new space and relocated ORA resident posts in Albany, NY; Harrisburg, PA; Scranton, PA; Charleston, SC; Grand Rapids, MI; and Laredo, TX to new GSA-owned or leased locations.
- Renewed leases for Springfield, IL Resident Post; New England District Office; Mayaguez, PR Resident Post; Dallas District Office; White Plains, NY Resident Post; Canoga Park, CA Resident Post; Los Angeles District Office; Los Angeles laboratory extended.

HEADQUARTERS CONSOLIDATION. Metro area consolidation activities continue on schedule.

- Continued to make progress on the design of the Phase I laboratory at White Oak. Phase I will result in approximately 110,000 square feet of space with occupancy projected for late 2002. Design of the Phase II CDER office space will begin in October 2000. Funding for FY 2000 included \$35 million for the construction of the CDER laboratory and the design of the CDER offices. The Phase II funding in FY 2001 is projected to be \$92 million for the construction of office space for approximately 1600 CDER employees and will result in the total consolidation of CDER at White Oak.



White Oak

- Construction continues at the College Park facility on the superstructure, building systems, and fit-out which will complete the building. As of August 15, 2000 the construction was approximately 60% complete. The contract completion is scheduled for October 2001. Occupancy will begin October 21 and be complete by February 2002.



College Park

ARKANSAS REGIONAL LABORATORY (ARL). Continued with the construction of the approximately \$38 million multi-purpose laboratory in Jefferson, Arkansas. The facility will assume many of the laboratory/analytical functions performed by the Chicago District laboratory and the analytical and laboratory functions from the Dallas, Minneapolis and Detroit laboratories when those facilities close, with the exception of Detroit's human drug functions and CDRH program work from Minneapolis. The dedication ceremony for the ARL building was held on February 17, 2000. The ceremony was attended by Representative Dickey and former U.S. Senator Bumpers of Arkansas and Commissioner Henney. ORA has moved equipment, furniture and personnel into the laboratory. The remaining Phase III work provides for the renovation of the existing Building 50, in its entirety and completion of the common ORA/NCTR administrative and support areas. Funding for the next portion of this work is expected in the FY 2001 appropriation.



Arkansas Regional Lab

NEW YORK (JAMAICA, QUEENS) LABORATORY. Dedicated the New York laboratory on May 2, 2000. Commissioner Henney led the ceremony, which was attended by congressional leaders, dignitaries from State and Local governments, and senior officials



New York Laboratory

from GSA and FDA. The building was awarded the Project of the Year in the institutional category by the Mayor's design construction industry organization – The New York Building Congress. York College is adjacent to the new building and has agreed to collaborate with FDA in terms of allowing students to work collaboratively with FDA personnel in the laboratories.

LOS ANGELES (IRVINE) LABORATORY. A solicitation for proposals was made available on May 22, 2000. The solicitation was issued in anticipation of an appropriation in Fiscal Year 2001 and to reduce the impact of procurement time on the project schedule. The solicitation was published on the FDA web page, the construction documents were made available, and proposals were received on August 24, 2000. FDA is utilizing a "best value" procurement to select a construction contractor for this project. It is anticipated that the award of the contract will occur early in Fiscal Year 2001.

DECOMMISSIONING OF FDA LABORATORY FACILITIES. Completed the decommissioning of the former Dallas District Laboratory, the former New York Regional Laboratory, and a portion of the space located at 4 Research Court in Rockville, Maryland. The decommissioning process was also initiated at one laboratory and continued at four additional laboratories being vacated as part of headquarters and field consolidation activities. In FY 2000, cost savings were realized from decommissioning process streamlining efforts undertaken in FY 1999. The period of time between the Phase II Environmental Site Assessment and the Phase III remediation activities was reduced by approximately 3 months. In the case of the New York facility, this resulted in a cost avoidance of \$514,316 in quarterly rent charges.

ENVIRONMENTAL, HEALTH AND SAFETY (EH&S) PROGRAM. Continued leading an effort to reinvent and reengineer the FDA EH&S Program, including changing the organizational culture as it relates to EH&S. FY 2000 accomplishments included: adding an EH&S component to the Agency level new employee orientation program; producing a video that will describe the Agency EH&S program to be used during orientation and re-orientation/awareness training activities; developing an EH&S information system to provide comprehensive data for effective decision-making, quality improvement, and organizational learning; and launching an EH&S home page on the FDA Intranet.

TECHNOLOGY TRANSFER/LEVERAGING. Continued to explore and actively encourage leveraging FDA assets such as enhancing the education/outreach program and identifying new ways for using existing mechanisms to leverage assets or defer costs. For example, continuing to work with the Office of Regulatory Affairs on the various implementation issues regarding the Cooperative Research and Development Agreement (CRADA) with EduNeering, Inc. The purpose of this CRADA is to establish a "virtual university" using an e-learning system for FDA's investigators and state inspectors nationwide. FDA managers, employees and their State counterparts will be able to take a course, access their training file, view their history and the courses they need to take, all in a virtual environment. Benefits of this partnership are increased effectiveness of the training and decreased time and travel expenses.

CFO AUDIT OF THE PROPERTY MANAGEMENT PROGRAM. Continued to strengthen FDA's management control and accountability for personal property and has built past year's successes.

- Improved FDA's Property Management program by continuing to implement new procedures such as an internal audit program. We have redelegated many property management functions, giving the customers greater control of their data. The CFO Auditor indicated that FDA appears to maintain sufficient oversight and control of property management transactions. Final audit results will not be known until the conclusion of the reverse and forward audits to be conducted by the independent outside auditor.
- Designed and implemented a tool to be used by center property management personnel to support effective property management performance. The new tool, the Center Report Card, allows each center to internally audit the effectiveness of their property management function.

MANAGEMENT OF PHYSICAL SECURITY. Diligently worked to provide for the security of FDA's people and property.

- Planned and coordinated security measures for controversial FDA meetings and Advisory Committee Hearings. This involved coordinated efforts with local police, intelligence authorities, Federal Protective Service authorities, and building security representatives to assure protection of FDA officials and panel members, and to prepare for any potential demonstrations against the Agency.
- Compiled and analyzed statistical data from employee surveys, with assistance from the Agency Security Task Group, to assess the physical security posture and identify any major security deficiencies within the Agency. Although most of the FDA employees that responded believe they are adequately protected at their workplace, there are areas that require some level of security enhancement to improve the overall physical security posture within the Agency. Implementation plans for corrective action are now under development to address these items.

• • Systems • •

AGENCY INFORMATION MANAGEMENT SYSTEM (AIMS). The AIMS initiative integrates database tracking, records management, electronic document management, electronic workflow. It also provides a tool for searching, retrieving and disseminating documents to FDA personnel and the public.

- Implemented an Electronic Submission Form and Registration Form on the Internet to allow the public to electronically submit responses to the Dockets Management Branch (DMB).
- Implemented an Intranet-based electronic document management application to provide Agency staff with immediate on-line access to records received by the DMB and the current files included in Title 21 of the Code of Federal Regulations.
- Tested and preparing to implement the automated publishing and subsequent relocation of data from the document management application to the Internet to expedite on-line access by the public.
- Currently testing a newly-developed Documentum application for the Office of the Executive Secretariat as a proof-of-concept that interfaces with the legacy Correspondence Tracking System and has the capability to perform a wide range of document management tasks. After implementation, it will be available to all offices using CTS.
- Implemented a tool to manage the bulk loading of files and data into the document management application in order to expedite on-line access by Agency staff.

TELECOMMUNICATIONS. Proceeding with the migration to the FTS2001 contract. All services are scheduled to be converted prior to the end of the FTS2000 contract in December 2000.

- Completed the TIP inventory project. All TIP lines have been inventoried, suspended, and those lines not restored have been disconnected.

TIP Lines in FDA

	Approximate # of Lines*	Annual Cost
FY99	10,000	\$3,000,000.00
FY00 (after disconnection of unused lines)	8,530	\$2,559,000.00
Annual Savings		\$441,000.00

*numbers are approximate as lines are added and subtracted every day

- Initiated the transition of FDA long distance voice services, wide area network, "800" services and credit card services from AT&T to MCI. The Agency is on target to have all services operational on the FTS2001 contract by the end of December 2000.
- Leased Fiber Services and Support. Installed state-of-the-art Giga-Switch technology at the Network Control Center (NCC) that provides 100 mb fiber connectivity between the CDER, CDRH, CBER Metropolitan Area Networks and FDA Headquarters. The fiber installation substantively increases the bandwidth, which allows Centers to transfer large review documents (IND's, NDA's, etc.) over their local area networks.

IT SECURITY: Presidential Decision Directive 63 (Cyber Terrorism). Ongoing efforts to comply with the directive include the completion of the installation of new firewall hardware and software technologies aimed at detecting and deterring unauthorized network access and denial of service attacks.

- Initiated development of policies and procedures to respond to and report network security threats and virus attacks.
- Completed physical and system security audits to evaluate access controls to ensure that FDA's information is not compromised by internal or external threats.
- Implemented firewall technology and successfully defended the Agency against the "Melissa" and "I Love You" virus attacks.

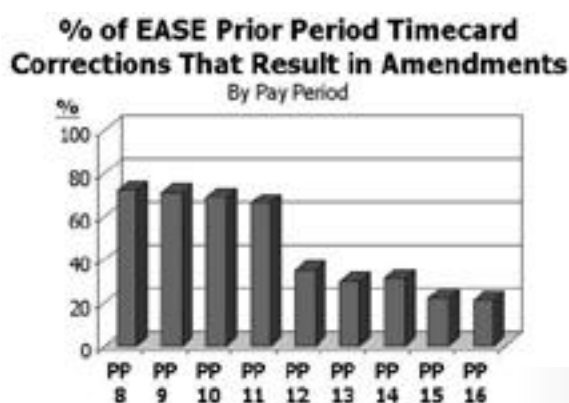
YEAR 2000 (Y2K) COMPLIANCE. Provided leadership and focus to: complete the Agency's Y2K remediation program; and establish the Agency's Y2K Day One program for final verification and validation of Y2K compliance. Specific OMS Y2K accomplishments are as follows:

- Coordinated a successful FDA-wide Y2K transition which included upgrading or purchasing 8,324 PCs for the Agency;
- Developed a comprehensive Agencywide plan for the "Day One" program, encompassing all testing and verification activities required to ensure the Agency's critical IT infrastructure (wide area network (WAN), mission critical local area networks (LANs) and supporting components, representative mission critical application systems, and mission critical building systems) were Y2K compliant prior to the first working day of 2000;
- Developed project management infrastructure for the "Day One" program to ensure effective coordination of multiple simultaneous testing, verification and remediation activities involving over 200 personnel Agencywide;
- Established and fully equipped "Day One" Command Center, which was the central communication hub for all Agency "Day One" activities;
- Successfully executed the "Day One" plan, ensuring plan objectives were met on schedule, timely status reports were delivered, and communication occurred to the Department throughout the "Day One" period; and
- Eased the burden of the "Day One" requirement on the Agency by helping to successfully justify to OMB the need for \$878,415 from the Y2K Emergency Supplemental fund to support the planning and preparation efforts of the Day One program.

ENTERPRISE ADMINISTRATIVE SUPPORT ENVIRONMENT (EASE).

- Completed rollout of EASE to all Centers, OC and ORA Headquarters and began rollout of EASE to the Field.
- Trained over 300 Reporting & Analysis Module (RAM) users.
- Implemented RAM history universe.

- Implemented interfaces from EASE Core to a number of systems, including the FDA E-mail directories, AIMS, and the DHHS Internet location directory.
- Worked extensively with OFM and PSC to implement program code changes that significantly reduced the percentage of EASE prior period timecard corrections that must be handled manually due to limitations of the payroll system. This has provided a reduction of 70% in the amount of manual paperwork and processing, freeing up over 3,100 hours for timekeepers and payroll personnel to carry out other duties. The new program code was implemented during pay period 12 processing and the accompanying chart illustrates the reductions since that time.

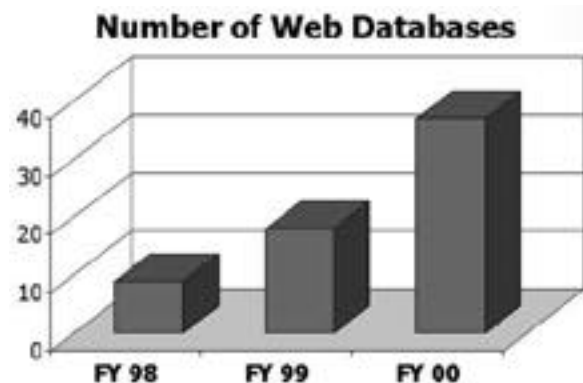
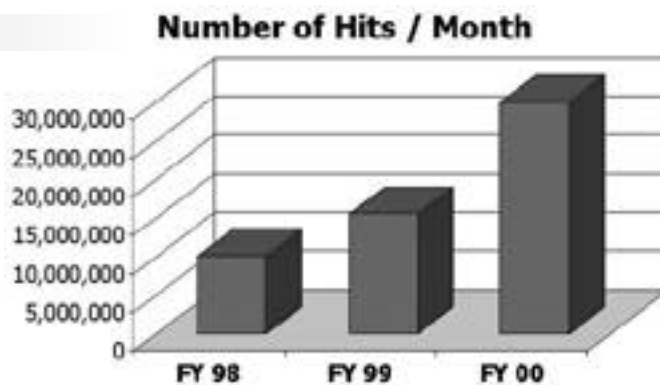
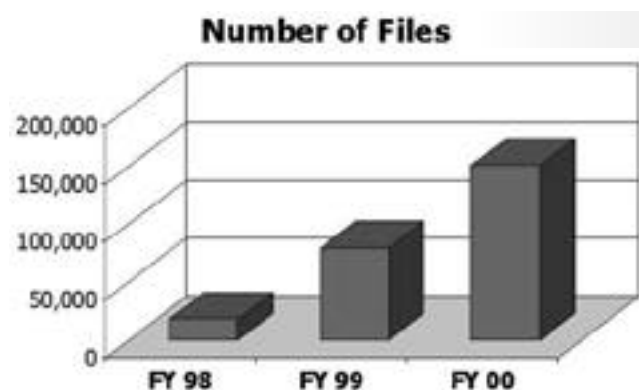


IT INVESTMENT MANAGEMENT. Continued to facilitate an IT Investment Management Process that ensures IT projects and resources are managed in an effective manner as required by the Clinger-Cohen Act. Improved the communication, understanding and participation with program areas through an Agency Re-engineering Team, which addressed how data call reporting burdens can be reduced.

- Facilitated a series of reviews and deliberations by the FDA's Information Technology Investment Review Board (ITIRB) that focused on the allocation of FY2000 strategic system reserve and equitably authorized \$6.5 million across nine key IT investments.
- Developed a proof-of-concept web-based capital planning tool to capture existing investment information and help produce standardized routine reports for external distribution to DHHS and OMB.

INTERNET/INTRANET SERVICES AND SUPPORT. The FDA public web site provides critical health information to the public and offers information of interest to health professionals, patients, consumers, industry, state, and local officials and many others. The

Internet web infrastructure has supported FDA by providing rich functionality, responding to changing needs, and by providing high performance, scalability, and reliability. In FY 2000, OMS significantly expanded the FDA Internet web site infrastructure and services provided to FDA developers and the public while still remaining within budget. In addition, OMS added additional application and database servers to support additional web-enabled databases, and to provide developers with a platform for placing Oracle database applications on the public web site.



Major Challenges for FY 2001

OMS is proud of FDA's FY 2000 managerial accomplishments and looks forward to the challenges ahead. In FY 2001, OMS will continue to work with FDA's management team as well as our employees, colleagues, and customers to position the Agency to meet the 21st century. With state-of-the-art technology, redesigned cost management systems, streamlined business processes, and innovative approaches OMS plans to meet and exceed our customer needs with fewer resources. A discussion of some of the high priorities on which OMS plans to focus in FY 2001 follows.

•• People ••

QUALITY OF WORK LIFE (QWL). Continue efforts to improve the Quality of Work Life for FDA employees by partnering with NTEU to address areas identified as needing improvement in the Human Resources Management Index, establishing an Elder Care Directory and providing elder care education to employees, developing and presenting a "How the Agency Works" seminar series to employees with 3-5 years of service, and implementing the priority recommendations of the QWL Communications Team.

STRATEGIC WORKFORCE PLANNING INITIATIVE ROLL-OUT. Establish an OMS Task Force to assist Centers/Offices in developing action plans, develop and distribute guidance and information, establish a compendium of workforce planning "best practices", and coordinate an Agencywide Corporate University.

PARTNERING WITH NTEU. Continue our successful partnering and pre-decisional involvement with NTEU including:

- Develop and implement a Child Care Subsidy Program
- Facilitate development of partnership councils throughout FDA and provide training on conflict resolution, interest based bargaining, and problem solving and decision making
- Maintain a collaborative and pre-decisional relationship with NTEU to solve problems and address issues through partnership rather than through third-party intervention

ENHANCING PDUFA. Implement ideas for enhancing retention of drug reviewers by implementing innovative ideas that flow from a series of focus groups to be conducted early in FY 2001 with drug application reviewers and with managers and supervisors of reviewers. Retention bonuses and sabbaticals are among the innovations we're preparing for, and there may be many others. Also, a major challenge will be to enable reviewers to conduct reviews and access agency files and systems from remote locations while at the same time assuring the security of both the agency files and the remote access hardware and communications. Another major challenge will be developing plans and strategies for the agency as we approach the expiration of the current PDUFA statutory authority in FY 2002.

RECRUITMENT AND STAFFING AUTOMATION. Obtain approval and funding for a system that automates, to the maximum extent possible, the recruitment and staffing processes (e.g. receiving applications via the Internet and electronically handling applicant rating and ranking), and then testing and implementing the system Agencywide.

HIRING PROGRAMS. Increase and expand the use of hiring programs for minority and disabled student interns, and establish formal partnership agreements with Historically Black Colleges and Universities (HBCU) and Hispanic Serving Institutions (HSI.)

DELEGATIONS OF AUTHORITY. Initiate a comprehensive project to update, reorganize and propose renumbering of FDA's delegations, by functional categories (i.e., drugs, biologics, foods, devices, etc.). The long range goal is to discontinue publishing the delegations under Title 21, Code of Federal Regulations (CFR), Part 5 and utilize the existing 1410 series of the Agency's on-line Staff Manual Guide System for publication. This would eliminate the cost of publishing the information in the Federal Register and CFR; allow for more timely updates; and improve access to the most "up-to-date" information. This project is a collaborative effort between OMS, the Regulations Policy and Management Staff, and the Office of Chief Counsel. Also, Agencywide coordination will be conducted.

• • Money • •

STRENGTHENING RELATIONSHIPS WITH APPROPRIATION COMMITTEES

STAFF AND OTHERS. Strengthen communications with the Congressional subcommittees, DHHS and OMB customers to increase knowledge of the Agency's mission goals and public health initiatives through the Congressional Justification, briefings, and background information.

Strive to improve the internal Agency budget process, enhancing the product while minimizing the burden on Center budget and planning staffs, and satisfying Congressional customers' needs.

Continue work with the Office of Planning to make the major budget and performance plans more congruent and complimentary of each other.

FINANCIAL MANAGEMENT IMPROVEMENTS. Provide Center managers with the tools to efficiently manage payroll resources through web-based technology. These tools will assist Center management in making resource decisions for supporting its program mission.

Strive to maintain current financial management service levels to the Centers while facing declining resources. This will be achieved through re-engineering of financial transaction processes or management procedures. Travel Manager software is being implemented to reduce the number of transaction numbers, reimburse the traveler sooner, and to provide a clean audit trail. Implementation procedures include posting various expense types to one Common Account Number to improve the timeliness of vendor payments and reduce the amount of interest paid.

CHIEF FINANCIAL OFFICERS ACT AUDIT. Leverage a department-wide financial systems workgroup effort to review financial system models for consideration by FDA and other operating divisions who are replacing their core accounting system. Cost savings are anticipated when the Agency makes a selection as the cost-benefit analysis will have been prepared and submitted by the workgroup's contractor and can be used by all participating OPDIVS.

Develop a business case report incorporating the internal customers' needs assessments, results from the HHS financial systems workgroup, the recommended financial system's model, and related cost-benefit analysis that will be used to select, fund, and procure the new core accounting system by FY 2002. Our goal is to implement a system that will improve response time for payments, reduce resources devoted to transactional activities and improve accounting resources.

•• Things ••

FACILITIES IMPROVEMENTS. Continue support for facilities improvements. The Agency will be involved in a number of large, complex facility improvement projects during FY 2001:

- LOS ANGELES (IRVINE) LABORATORY

The contract for this project will be negotiated and awarded early in Fiscal Year 2001. Construction will begin on the first phase of the project that involves site work, construction of the building's structure and exterior walls. As an FDA funded project, the administration of the contract will continue over the next two years.

- WHITE OAK PROJECT PLANNING

The FDA consolidation at White Oak is a five phase project requiring over \$580 million in appropriations. Phase I and phase II of the project have received appropriations for design and construction from Congress. Construction for phase I and design of phase II will occur concurrently. The design and construction activities will result in the development of nearly 600,000 gross square feet for over 1900 FDA employees. Monitoring the phase I construction and the high level of FDA participation needed for phase II design will require substantial resources from OMS staff. Analysis of operational and logistical activities will also require extensive OMS resources. Planning efforts will continue requiring cost estimating and validation of phase III budgets and the adjustment of the overall master plan to reflect changing employment within the Agency. This variety of activities which involves concurrent planning design and construction will be a continued focus for OMS.

- COLLEGE PARK MOVE

The construction of CFSAN's College Park facility is planned for completion by October 2001, and will require substantial resources from OMS staff. A four-month time span has been projected for accomplishing the CFSAN move. Relocation will require vacating two leased locations and Federal Building 8 in the District of Columbia and occupying the MOD I building, the Beltsville Research Facility, the new government constructed College Park building and a small building to be leased in the College Park vicinity. A schedule pertaining to the College Park move has been prepared that details the sequence of activities and their interrelationships, beginning

in December 2000 and ending in March 2002.

- **MOD I AND THE BELTSVILLE RESEARCH FACILITY (BRF) RENOVATIONS**

Pre-project planning with CDER and CFSAN to address the feasibility of accomplishing major renovations to a portion of both the MOD I and BRF buildings. The pre-project planning involved coordination with CDER that presently occupies the space and CFSAN organizations that will be the future occupants. Renovations of the buildings is required to accommodate CFSAN organizations because they are located in Federal Building 8 in Washington D.C. which will be closed in 2002. This effort must coincide with the timeframe for CFSAN's relocation to College Park. In addition, efforts are underway to acquire leased laboratory and office space for CFSAN adjacent to the College Park site.

CFO AUDIT - PERSONAL PROPERTY. Continue process improvements to ensure clean CFO Audit results. This can be achieved by maintaining a "0" Defects approach to each separate property transaction starting with acquisition through management and disposition. Maintain the current focus on agency component's inventory accountability and training requirements. Successfully implement the integration of the personal property, finance, and acquisition information system. Continue to implement the personal property reengineering initiatives aimed at improving operational efficiencies and at reducing operational costs.

AUTOMATED SYSTEMS. Implement a variety of administrative systems. These new systems will provide for increased delegations to the Centers and ORA, time savings across the agency, and better oversight of our program areas. They include:

- **FACILITY CENTER:** FDA has purchased software to expand the existing facilities management system to an Agencywide system through the web capabilities of the enhanced software version. The new system (Facility Center) will allow OFACS and the centers to maintain a comprehensive database on all FDA facilities nationwide, to include CAD drawings where available for space planning and design, help desk capabilities, building operations and maintenance information, building leases and pertinent lease information.
- **PURCHASE REQUEST INFORMATION SYSTEM IMPLEMENTATION:** Complete pilot testing of the automated procurement system, PRISM, and roll out the system to the Agency. Interface system to the property, finance and departmental contract information systems.

GRANTS ADMINISTRATION AUTOMATION AND IMPROVEMENTS. The number of grants FDA processes each year continues to climb. We plan to explore ways to redesign and streamline the way we do business with our customer communities. Some areas we are looking at include:

- Assess existing grants management systems that could support FDA's grant management work functions without reinventing the wheel. Explore the possibilities of electronic imaged record storage.
- Collaborate with NIH's ongoing interagency development of the Federal Commons. The Federal Commons is an Internet-based point of entry for grant preparers and recipients to conduct business electronically with Federal grant making agencies.
- Work with management and program Staff to promote more and better advance planning in future fiscal years to eliminate the end of the fiscal year crunch during 4th quarter.
- Work with ORA to initiate a fixed price grant concept Request for Applications.
- Work with our program offices in developing an orientation handbook for reviewers on FDA's application and peer review process.
- Revise the Support of Scientific Conferences grant RFA to include funding for up to three (3) or five (5) years (multiple year awards) to a sponsoring organization for conferences held annually or biennially on a recurring topic.

DELEGATIONS. Expand existing delegations to Center and ORA personnel. These increased delegations will enable OFACS to focus on larger, bigger picture projects and will ensure that the needs of the Agency are met without increasing staff.

IMPAC PROGRAM. Explore the development of Web-base training for new cardholders, approving officials and central control points. The training vehicle would also be used as a refresher course for existing participants in the program. This method would reduce time and man-hours.

SIMPLIFIED ACQUISITION AUTHORITY. Increase Center Purchasing Agent simplified acquisition authority up to \$100,000. Increase authority will require additional Department of Health and Human Services Training and onsite training by OFACS for each individual purchasing agent.

REAL PROPERTY REENGINEERING. Implementation of the 31 recommendations from the space management reengineering effort to include the facilities help desk and the integration and expansion of the automated facilities management system Agencywide.

•• Systems ••

CYBER TERRORISM (PRESIDENTIAL DECISION DIRECTIVE 63). Strengthen defenses from cyber terrorism through:

- Complete development of an Agency Critical Infrastructure Protection Plan;
- Implementation of a secure remote dial-in solution for the Agency which will allow for secure connectivity to the Agency network by utilizing technologies such as Virtual Private Networks;
- Identification and deployment of a secure e-mail and encryption software to allow for the transmission of confidential and trade secret data between parties who have a need to know; and the
- Enhancement of the Agency firewall infrastructure to increase capacity and response times to the Internet.

INFORMATION SYSTEMS ARCHITECTURE (ISA).

- Develop and implement a comprehensive secure remote access system for the Agency. Information Security is evolving into an increasingly complex system of countermeasures against intrusion of malicious external sources. As requirements for Flexiplace and mobile computing increase, the need to provide accesses more efficiently and securely becomes more pressing.
- Promote complete implementation of ISA components by the entire Agency. Vast changes have occurred since the beginning of this project that have brought most of the Agency's Architecture into a common environment where the moving of information throughout the Agency, the industry it regulates, and to the general population that it serves is commonplace.
- Begin evaluation of the next generation of the ISA standard software packages. ISA now has the task of building on the original components. Focusing on examining the

Agency's growing IT needs and the protection of those assets. As a result of the ever changing face of technology and the continually increasing threat of unauthorized access to sensitive data on Agency assets and infrastructure, ISA has reevaluated the established standards and has increased the threshold for essential components.

- Develop a migration strategy and architecture for the Windows 2000 implementation in FY 2002. With all the changing technologies, the evolution of the Operating System component of the ISA standard has also occurred. The evolution of the Operating System to Windows 2000 is a giant step in the modernization of Agency information technology and how collaboration and workflow can be used.

TELECOMMUNICATIONS and NETWORK

- Complete implementation of new network architecture for the Agency.
- Develop and meet project milestones for the White Oak campus consolidation.
- Complete implementation telecommunications cabling and wiring of the College Park/CFSAN facility.
- Install and manage telecommunications equipment between Booze, Allen & Hamilton and Federal Express to allow for the exchange of data and electronic screening of FedEx import shipments between ORA and Federal Express.
- Provide assistance to ORA in the design and implementation of a secure remote connectivity solution to meet the ORA requirement of providing State inspectors direct access to the ORA FACTS system from designated State facilities and remote locations. OIRM will be providing the installation and maintenance of the initial secure interface to the FDA network.

ENTERPRISE ADMINISTRATIVE SUPPORT ENVIRONMENT (EASE)

- Complete rollout of EASE to Field, making FDA 100% on EASE (over 9,000 employees) and ending manual timekeeping system.
- Make 15 years of ARIES historical data available through EASE RAM.
- Web-enable EASE.

- Work to leverage the FDA investment in EASE data by reusing it through interfaces of integration with other applications such as Travel Manager and the OFACS property and space management systems. Continue providing online interface of EASE CORE data to AIMS and new AIMS modules. Continue providing CORE personnel, e-mail and location data to the FDA E-mail directory and the DHHS Internet location directory through batch interface files. Begin populating contractor data in EASE for interface to the badge system and security clearance system.

AGENCY INFORMATION MANAGEMENT SYSTEMS (AIMS)

- For the Federal Register program areas, develop new database application and integrate it with Documentum, document management and workflow. Implement it in OC RPMS and Centers Federal Register staffs. This will include development of an application for creating and tracking changes to the CFRs. This application will provide access to all current CFRs and proposed changes to FDA personnel via the FDA Intranet.
- For the Dockets Management Branch (DMB), develop Documentum application for scanning in documents, entering data and interfacing with existing Dockets applications. Add functionality to store Advisory Committee, NADA's, and other DMB documents into the Documentum application including search and retrieval capability. Enhance the on-line electronic submission of public comments to dockets and the off-line template for use on all dockets.
- For Freedom of Information (FOI) program areas, develop an electronic FOI request form that is integrated with the FOI tracking system. Implement Documentum application for the scanning and storage of all FOI requests and responses.
- Provide capability to automatically post to and remove from the FDA Internet selected documents contained with the Documentum applications.

INTERNET/INTRANET SERVICES AND SUPPORT

- Provide hardware/software and connectivity to support 35 gigabytes of web documents (growing at a rate of one gigabyte monthly), 35 web-enabled databases, and over 90 gigabytes of data transferred monthly; and implement new requirements.
- Create a secure Internet environment that fosters collaboration and allows electronic collecting and exchange of data directly from sources outside of FDA (public, states

and industry, etc.). This will be achieved through the implementation of an infrastructure with its own dedicated network, firewall system, high-end encryption capabilities, and a secure end-to-end connection between FDA and the hosting company.

- Select, procure and implement collaboration software to automate the manual processes involved in creating and placing information on the FDA web site. This will reduce the time and effort spent managing 125,000+ static web documents and will improve the presentation, quality, access to, and speed of delivery of the information on the FDA web site.
- Establish standards and guidelines to prioritize the implementation of new web-enabled databases and identify and integrate crosscutting applications.

For More Information

The OMS team is pleased to work with all FDA personnel as we strive to protect, promote, and enhance the health of the American people. For more information about OMS services and systems, please contact:

- Deputy Commissioner for Management and Systems, (301) 827-3443
- Director, Office of Human Resources and Management Services, (301) 827-4120
- Director, Office of Financial Management, (301) 827-5001
- Director, Office of Facilities, Acquisitions, and Central Services, (301) 827-6890
- Chief Information Officer, (301) 827-4280

Additional information about OMS programs is also available on FDA's Intranet (<http://learnfda.fda.gov>), and on the Internet (<http://www.fda.gov>) for information on PDUFA, Dockets Management, and the Yellow Book.